A SYSTEM FOR MONITORING CONDUIT OBSTRUCTION

REFERENCE TO PREVIOUS APPLICATIONS

This application claims the benefit of United States Provisional Applications No. 60/416,406 filed on October 7th, 2002, 60/416,407 filed on October 7th, 2002, 60/416,408 filed on October 7th, 2002, and 60/416,409 filed on October 7th, 2002.

FIELD OF THE INVENTION

The present invention relates generally to field of implantable medical devices for monitoring physiological parameters. More particularly, the invention relates to a system utilizing a telemetric implantable physiologic sensor for diagnosing and/or monitoring the conduit obstruction and/or insufficiency in patients that have undergone cardiac conduit surgery.

BACKGROUND OF THE INVENTION

Certain heart defects require implantation of a conduit for blood flow to bypass valve aplasia or severe stenosis. These include but not limited to cases of a pulmonary artery only with no aorta. The added conduit may or may not include a valve.

There are several types of conduits, including but not limited to:

Homograft – from the same species (i.e. another human)

Heterograft – from a different species (e.g. pig)

Artificial – man-made materials (e.g. Gortex)

Combination of two or more of the above.

In any case, the conduits may eventually become calcified and/or stenotic. Currently, cardiac catheterization, Doppler echocardiography, and/or Magnetic Resonance Imaging (MRI) are used to assess the degree of stenosis. Catheterization gives the best assessment, since it can directly measure the pressure gradient across the conduit; however, it carries progressive morbidity and mortality. Furthermore, all three methods require specialized equipment and they provide only a snapshot of the physiologic status.

Occlusion is an eventuality in nearly all conduit cases; the question is only a matter of when it will occur. The impact of occlusion includes right ventricle (RV) failure. Treatment for occlusion is to replace the conduit entirely. Physicians need a means of noninvasively, accurately monitoring conduit condition on a continuous basis in order to determine whether and when conduit revision is required. Furthermore, remote monitoring of conduit condition would simultaneously reduce the number of hospital and clinic visits while increasing the overall timeliness of treatment.

SUMMARY OF THE INVENTION

The invention comprises a telemetric sensing system for noninvasively monitoring pressure and/or pressure gradients in a cardiac conduit. The system includes one or more implantable sensor unit(s) and a companion reader unit. The batteryless, wireless pressure sensor unit(s) is chronically located within the conduit, or around in a close proximity. For valveless conduits, a sensor is placed at either end of the conduit, or around it. For valved conduits, one or more sensors are located both proximal and distal to the valve, allowing the pressure gradient across the valve to be monitored. One sensor can indicate occlusion; however, two sensors will allow the occlusion to be located (e.g. proximal/middle/distal along the conduit). As well, with two sensors, flow rates may be deduced or estimated. Furthermore,

trend analysis of the pressures and/or flow rate within the conduit can allow a time-to-failure estimate.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 is a schematic of an implantable pressure monitor fixed in a cardiac conduit.

Figure 2 is a block diagram of a magnetic telemetry based physiologic monitoring system based on a resonant scheme according to a preferred embodiment of the present invention.

Figure 3 is a block diagram of a magnetic telemetry based physiologic monitoring system based on a passive scheme according to an alternate embodiment of the present invention.

Figure 4 is a perspective view of a sensor implant incorporating a screw anchoring mechanism according to a preferred embodiment of the present invention.

DETAILED DESCRIPTION OF PREFERRED AND ALTERNATE EMBODIMENTS OF THE INVENTION

The following description of preferred embodiments and methods provides examples of the present invention. The embodiments discussed herein are merely exemplary in nature, and are not intended to limit the scope of the invention in any manner. Rather, the description of these preferred embodiments and methods serves to enable a person of ordinary skill in the relevant art to make, use and perform the present invention.

In order to provide for the effective monitoring, management, and tailoring of treatment for patients with heart defects, the present invention provides a wireless sensing system. The system comprises an external readout unit as well as one or more implantable pressure monitor **50** which is securely anchored in a conduit **60**, as shown in Fig. 1 or in the vicinity of the conduit. The readout unit both transmits power to and receives transmitted data from the implant. Data transmitted from the implantable device may include pressure, calibration data, identification

data, fluid flow rate, and/or other physiologic parameters. The readout unit may include a barometric pressure sensor in order to compensate for variation in atmospheric pressure.

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The batteryless, wireless telemetry link is preferably implemented using either a resonant or passive, magnetically coupled scheme. A resonant device **101** (shown in Figure 2) is the simplest approach, and consists only of a packaged inductor coil **103** and capacitive pressure sensor **102**. Together, the two elements form a circuit that has a specific resonant frequency. At that resonant frequency, the circuit presents a measurable change in magnetically coupled impedance load to an external coil. Because the resonant frequency is a function of the coil inductance **103** and the sensor capacitance **102,** as pressure changes the resonant frequency changes as well. An external reader **104** is able to determine pressure by monitoring the frequency at which the coil antenna **105** impedance changes.

The preferred communication scheme for the present invention, shown in Fig. 3, is based on magnetic telemetry. Devices that have on-board circuitry but still receive their operating power from an external source (i.e., are batteryless) are referred to as passive devices **201** (shown in Figure 3). Without an external reader present, the implant device **201** lays passive and without any internal means to power itself. When a pressure reading is desired, the reader device **202** is brought into a suitable range to the implant. In this case the

external reader **202** uses an alternating magnetic field to induce a voltage in the implant. When sufficient voltage has been induced in the implant **201**, a rectification circuit **203** converts the alternating voltage on the receiver coil **204** into a direct voltage that can be used by the electronics **205** as a power supply for signal conversion and communication. At this point the implant **201** can be considered alert and, in the preferred embodiment, also ready for commands from the reader. The maximum achievable distance is mostly limited by the magnetic field strength necessary to turn the implant on. This telemetry scheme has been proven and used extensively in the identification and tracking industry (e.g., implantable RF ID technology from Texas Instruments or Digital Angel) with a great deal of acceptance and success.

Once the direct voltage in the implant has been established for the circuit operation, a number of techniques may be used to convert the sensor output into a form suitable for transmission back to the reader device. In the preferred embodiment, a capacitive pressure sensor **206** and sigma delta conversion or capacitance to frequency conversion of the sensor output may be easily used. Capacitive sensors are preferred due to the small power requirements for electronics when reading capacitance values. Many pressure sensors are based on piezoresistive effects and, while suitable for some applications, do suffer in this application due to the higher power levels needed for readout. Sigma delta converters are preferred due to the tolerance of noisy supply voltages and manufacturing variations.

As those skilled in magnetic telemetry are aware, a number of modulation schemes are available for transmitting data via magnetic coupling. The preferred schemes include but are not limited to amplitude modulation, frequency modulation, frequency shift keying, phase shift keying, and also spread spectrum techniques. The preferred modulation scheme may be determined by the specifications of an individual application, and is not intended to be limited under this invention.

In addition to the many available modulation techniques, there are many technologies developed that allow the implant to communicate back to the reader the signal containing pressure information. It is understood that the reader device may transmit either a continuous level of RF power to supply the implant's needed energy, or it may pulse the power allowing temporary storage in a battery or capacitor device. Similarly, the implant **201** of Fig. 3 may signal back to the reader **202** at any interval in time, delayed or instantaneous, during reader RF (Radio Frequency) transmission or alternately in the absence of reader transmission. The implant **201** may include a single coil antenna **204** for both reception and transmission, or it may include two antennas, one each for transmission **204** and reception **221**. There are many techniques for construction of the reader coil **219** and processing electronics known to those skilled in the art. The reader **202** may interface to a display, computer, or other data logging devices **220**.

The electronic circuit may consist of a receiving inductor coil **204**, rectification circuitry **203**, signal conditioning circuitry **211**, and signal transmission circuitry **212**.

A large number of possible geometries and structures are available for receiver coil and known to those skilled in the art. The coil conductor may be wound around a ferrite core to enhance magnetic properties, deposited on a flat rigid or flexible substrate, and formed into a long/skinny or short/wide cylindrical solenoid. The conductor is preferably made at least in part with a metal of high conductivity such as copper, silver, gold. The coil may alternately be fabricated on implantable sensor substrates. Methods of fabrication of coils on the sensor substrate include but not limited to one or more or any combination of the following techniques: sputtering, electroplating, lift-off, screen printing, and/or other suitable methods known to those skilled in the art.

The rectification circuitry **203** outputs a constant voltage level for the other electronics from an alternating voltage input. Efficient realizations of such circuitry are standard electronic techniques and may include either full bridge diode rectifiers or half-bridge diode rectifiers in the preferred embodiment. This rectification circuitry may include a capacitor for transient energy storage to reduce the noise ripple on the output supply voltage. This circuitry may be implemented on the same integrated circuit die with other electronics.

The signal conditioning circuit **211** processes an output signal from the sensor **206** and prepares it for transmission to an external receiving and/or analyzing device. For example, many pressure sensors output a capacitance signal that may be digitized for radio frequency (RF) transmission. Accordingly, the signal conditioning circuit **211** places the output signal of the sensor into an appropriate form. Many different signal conditioning circuits are known to those skilled in the art. Capacitance to frequency conversion, sigma delta or other analog to digital conversion techniques are all possible conditioning circuits that may be used in a preferred embodiment.

The signal transmission circuitry **212** transmits the encoded signal from the signal conditioning circuitry for reception by an external reader. Magnetic telemetry is again used for this communication, as the transmission circuitry **212** generates an alternating electromagnetic field that propagates to the reader **202**. Either the same coil **204** is used for signal reception and for transmission, or alternately a second coil **221** is dedicated for transmission only.

A third option, particularly useful for (but not limited to) situations in which long-term data acquisition without continuous use of the readout unit is desirable, is to implement the sensor using an active scheme. This approach incorporates an additional capacitor, battery, rechargeable battery, or other power-storage element that allows the implant to function without

requiring the immediate presence of the readout unit as a power supply. Data may be stored in the sensor and downloaded intermittently using the readout unit as required.

The implantable sensor may be physically realized with a combination of any of several technologies, including those using microfabrication technology such as Microelectromechanical Systems (MEMS). For example, capacitive and piezoresistive pressure sensors have been fabricated with MEMS technology. A hermetic sensor package may be formed from anodically bonded layers of glass and boron-doped silicon, which is further incorporated into the Fontan baffle structure.

Anchoring provisions may be incorporated directly into such a hermetic package, or they may alternately be added with an additional assembly step. An example of this would be insertion of the package into a molded plastic or metal shell that incorporates anchoring provisions. Possible anchoring methods include those conventionally used for cardiac pacing leads, such as screws or tines, as well as septal occluder schemes. Many such packaging schemes are known to those familiar with the art, and the present description should not be construed as limiting.

Pacemaker leads have a well-established history for implantation methods, and similar techniques are possible for the current invention. A screw **13** (Figure 4) or barb may be used to attach the implant to a heart or vessel wall. In the first package option shown in Figure 4, a screw **13** may be molded into the device shell **26**, and screwed into the ventricle wall so that that the screw buries below the wall surface. In addition, the package may have mesh **25** attached to the device to promote tissue growth and anchoring.

In addition to the basic implant-and-reader system, a number of other embodiments of the technology can be realized to achieve additional functionality. The system may be implemented as a remote monitoring configuration, including but not limited to home monitoring,

which may include but not limited to telephone based, wireless communication based, or web-based (or other communication means) delivery of information received from the implant by the reader to a physician or caregiver.

The implantable sensor can be any suitable miniature sensor adapted to detect and/or monitor various physiological parameters. For example, the sensor can comprise a pressure sensor, a temperature sensor, a flow sensor, a velocity sensor, or a sensor adapted to measure specific chemistries such as gas content (e.g., $O2$ and $CO2$) and glucose levels. Various specific examples of these types of miniature sensors are known to those skilled in the art, and any one or more of these suitable sensors can be utilized in the sensor module of the present invention. While the specific type of sensor(s) chosen will depend on the application of the implantable system, the sensor(s) should be of a sufficiently small size in order to facilitate placement within a catheter for delivery and implantation.

To limit the risk of thrombogenesis, the preferred embodiment has limited protrusion of volume into the blood stream (particularly in the left side of the heart), as both shape and size are factors in thrombogenesis. Another shell may be overmolded or preformed to house the glass/silicon module, and the outer shell contains the necessary apparatus for anchoring the implant. In a preferred embodiment, the outer shell may be formed with existing plastic injection technologies suitable for medical implantation. A coating, preferably of silicone, parylene and/or polymers provides a non-thrombogenic exterior for the biologic environment.

Note that in addition to sensing physiologic parameters, the described system could be augmented with various actuation functions. In such case, the implant device would be augmented with any of various actuators, including but not limited to: thermal generators; voltage or current sources, probes, or electrodes; drug delivery pumps, valves, or meters;

microtools for localized surgical procedures; radiation-emitting sources; defibrillators; muscle stimulators; pacing stimulators.

The foregoing disclosure includes the best mode devised by the inventors for practicing the invention. It is apparent, however, that several variations in the apparatuses and methods of the present invention may be conceivable by one skilled in the art. Inasmuch as the foregoing disclosure is intended to enable one skilled in the pertinent art to practice the instant invention, it should not be construed to be limited thereby, but should be construed to include such aforementioned variations.